

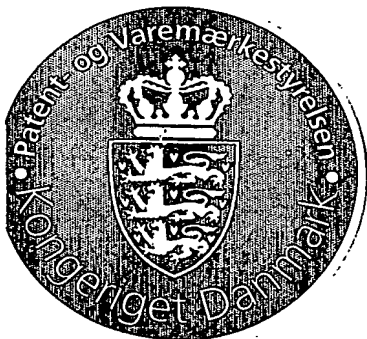
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29 January 2004

A handwritten signature in black ink.
Bo Zillo Tidemann

A DEVICE FOR OPENING A HUMAN BLADDER

Modtaget

20 DEC. 2002

Field of the invention

PVS

5 The present invention relates to a device for opening a bladder for draining fluids from the bladder. In particular, the invention relates to a device that can be arranged in a configuration wherein the size of the device is small in comparison with the size of known catheters, especially in comparison with existing catheters for male users.

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Background of the invention

Persons suffering from urinary incontinence or disabled individuals who may not be able to control urination normally use catheters to void their bladder. Existing
15 catheters are typically made from a single piece of a continuous catheter tube, and typically the thickness of the catheter tube is constant throughout its length. The length of the catheter is chosen to allow the catheter to be inserted into the urethra until the urine starts to flow. In addition, a certain over-length of the catheter is available for the manipulation and removal of the catheter. The over-length,
20 *inter alia*, supports the user to firmly hold the catheter, to guide the urine to a place of disposal and to withdraw the catheter safely, without any risk of the catheter disappearing into the urethra. The catheter is thus longer than the urinary canal and, especially for men, the total length of the known catheters prevents carrying and disposal of the catheter in a discrete manner.

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It is important that the tubular member does not collapse or kink, since this may cause problems during insertion and withdrawal of the catheter from a urinary canal and further may cause blocking of the passage for the urine to drain through the catheter. Existing catheters are therefore typically made from a form

stable and relatively hard but still bendable tube, e.g. made from PVC or polyurethane. Since the hardness of the catheter tube is selected relatively high with the view to avoid kinking or collapse of the internal flow channel, the catheters may collapse if they are bend with a too small radius of curvature. Accordingly, existing catheters not only have a considerable lengths but they are also typically packed in an elongate condition, and in order to maintain the functioning of the catheter, the user is prevented from bending such packages into smaller or less notable dimensions.

- 10 Therefore, the existing catheters may be troublesome to handle and to bring along, not least for the large group of catheter users, who make use of catheters on a daily basis.

Description of the invention

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It is an object of a preferred embodiment of the present invention to overcome the aforesaid disadvantages of the known catheters by providing a device for opening a human bladder comprising:

- 20 – an oblong member for opening the urethral sphincter, and
– a flexible guide member for manipulating the oblong member,

wherein the oblong member is shorter than the guide member, and the oblong member comprises means for draining fluid from the bladder.

25

Accordingly, a device allowing draining of the bladder is provided. Since the oblong member is manipulated via a flexible guide member, the oblong member can be provided in a length which is just sufficient to open the urinary sphincter and which is very short compared with the length of a regular catheter. In this connection, the sphincter means one of or both of the inner and the outer sphincter. In one embodiment, it may be an advantage to provide the oblong member in a

length sufficient to provide a free passage around prostate or even in a length which is sufficient to provide a free passage around prostate and simultaneously to open the sphincter. Due to the flexibility of the guide member it is possible to arrange the device in a configuration wherein the device is discrete and easy to
5 convey and dispose, e.g. in a configuration in which the guide member is rolled up or folded.

In a preferred embodiment of the invention, the guide member may be fixed to the oblong member. The guide member and the oblong member may be made as
10 one integral part, i.e. made in one piece. For example, the guide member and the oblong member may be cast together, or the guide member may be extruded from the oblong member. Alternatively, the guide member and the oblong member may be made separately, and afterwards, be firmly attached together. A firm and reliable joint can be achieved by, e.g., gluing or welding the two members
15 together. A reliable and secure joint between the oblong member and the guide member may be imperative in order to ensure that the oblong member can easily be removed from the urethra after the bladder has been voided. However, as will be discussed below, it may also be advantageous to provide an embodiment wherein the guide member is attachable to the oblong member, and further to
20 provide an embodiment where the guide member is also detachable, even during use. These aspects will be further elaborated upon below.

The guide member serves firstly to manipulate the oblong member, i.e. to insert the oblong member in the urethral sphincter so that the sphincter can be opened
25 and the bladder voided. The purpose of the oblong member is to provide a passage for urine through the sphincter. Since the oblong member is inserted into the urethral sphincter via the urinary canal, the oblong member should preferably have an outer cross-sectional size similar to the cross-sectional size of known catheters. The length of the oblong member should preferably be at least slightly
30 longer than the sphincter. Thereby, it is possible to hold the full length of the sphincter open while a part of the tip of the oblong member protrudes into the inside of the bladder. Alternatively, to hold the sphincter and the passage past

prostate open while a part of the tip protrudes into the inside of the bladder. The length of the oblong member may therefore be between 1 and 7 cm, such as between 3 and 5 cm.

- 5 In one embodiment, the passage for urine through the sphincter may be provided by at least one exterior conduit formed between a urinary canal of a catheter user and the catheter. In this embodiment, the conduit may be provided by one or more grooves starting at the tip or in the vicinity of the tip of the oblong member. In this respect, it may be an advantage to make a smoothly rounded tip. The
- 10 grooves should continue along the oblong member to a point sufficiently far away from the starting point to ensure that urine could pass the sphincter and/or prostate through the groove. The groove or grooves may follow a helix-like path along the outer surface of the oblong member or it may run in one or more straight or parallel lines along the outer surface of the oblong member. In the case of more
- 15 than one helix-like curved grooves, the grooves may run intertwined along the member. The groove(s) should be deep enough to allow fluids to flow steadily along the conduit(s) formed between the wall of the urinary canal of a catheter user and the catheter. In order to allow the urine to drain freely, grooves with a depth between 0.2 and 1.5 mm, such as between 0.3 and 1.2 mm, may be pro-
- 20 vided. The cross-sectional area of the groove or of the sum of the cross-sectional areas of all of the grooves should preferably be comparable to the cross-sectional area of the drainage conduit of catheters known *per se*. The edges of the grooves may be smooth in order to minimize the risk for irritation of the inside of the urinary canal due to a shape change in the oblong member. The grooves may ex-
- 25 tend to the outermost part of tip of the oblong member so that urine may flow as soon as the oblong member starts to protrude into the bladder. In a cross-sectional view of the oblong member, the groove or grooves may have a semi-circular shape, a heart shape, an oval shape, a V-shape or in fact any shape which allows urine to drain between the wall of the urinary canal and the catheter.
- 30
- In another embodiment of the oblong member, a conduit through the sphincter may be provided via a canal with at least one inlet opening and at least one outlet

opening which allows fluid to pass through the member, and thereby allows drainage of the bladder through the canal. With respect to the dimensions of the oblong member, regular catheter dimensions may be employed, i.e. the outer cross-sectional size and the cross-sectional size of the conduit may be chosen in accordance with existing standard sizes for regular catheters. The length of the oblong member may be in the range of 1-7 cm. such as in the range of 3-5 cm.

The oblong member should, irrespective of the embodiment, be form-stable in order to provide an opening of the sphincter, but also to substantially maintain its shape during insertion and retraction of the member. The oblong member is to be inserted into a urinary canal and therefore this part may be made in a flexible and resilient material so that, during insertion, it follows the course of the canal without posing substantial pain or malaise. The oblong member could be made from a thermoplastic elastomer or other thermoplastic materials or from a curable elastomer material or any mixture or combination thereof. Thermoplastic elastomer materials may comprise materials like Polyurethane elastomers (e.g. Estane™), Polyetherblockamide elastomers (e.g. Pebax™) Polyester elastomers (e.g. Hytrel™), polyolefin elastomers (e.g. Santoprene™ and e.g. Engage™), Polystyrene elastomers (e.g. Kraton™ compounds) and PP elastomers with controlled tactic and atactic domains. Other thermoplastic materials may comprise PVC, e.g. plasticised PVC, Polyethylene homo- or co-polymers, polypropylene homo- or co-polymers, Polyamide types, Polyester types, fluorine-containing thermoplastic materials such as fluorine-containing elastomers among others. Curable elastomer materials may comprise silicone elastomers and curable polyurethane elastomers among others.

The guide member should on one hand be able to support rolling up but on the other hand be rigid enough to support at least insertion of the oblong member, and in some cases also removal of the oblong member after the catheterization has ended. The guide member may be made from a metal or metal alloy with a flexibility permitting rolling up of the guide member. Alternatively, it may be made from a polymer material, either as a solid material, or as a hollow element. As an

example, the hollow element may be composed of two oblong concave profiles assembled along their longest edges to form a hollow, tubular member. The guide member may also be made from a composite material, such as kevlar™ or similar fibres as carbon fibres, polyester fibres or glass fibres. The fibres may be
5 embedded in a resin of the aforementioned kinds, e.g. in a polyester resin.

In order to facilitate the manipulation of the device, the guide member may comprise gripping means such as a ring into which a finger may be inserted, a knob, or such as an area in the distal end of the guide member which is provided with a
10 rough surface so that a firm grip may be facilitated due to increased friction in said end. In another embodiment, the guiding member may, at a non-insertable end zone, have a larger size, thus facilitating easier handling.

In the aforementioned embodiments, the urine should, after it has passed the
15 sphincter, continue its flow in direct contact with the urinary canal of the catheter user. Even though this may have a flushing effect which may have a positive bacteriological effect on the urinary canal, it may sometimes be an advantage to provide a slack tube for guiding the urine inside the urethra or similar urinary canal of the user. The slack tube enables that the urine can be drained to a place of disposal, e.g. to a collection bag. Thus, by providing a slack tube for guiding the urine,
20 a better control of the urine is obtained, especially if, e.g., the urine should be collected in a collection bag. Since the slack tube may extend outside the body, the slack tube may also be used for the extraction of the oblong member from the urinary canal. Accordingly, one preferred embodiment of the invention relates to a
25 device further comprising a slack tube providing an internal conduit for draining urine from the bladder. The slack tube should be arranged in relation to the oblong member so that the internal conduit is in fluid communication with a conduit of the oblong member. The urine after it has passed the sphincter via the oblong member, is at one proximal end of the slack tube collected inside the conduit
30 thereof and drained out of the urinary canal inside the slack tube. At the other distal end of the slack tube, the urine may be drained into a place of disposal such as a lavatory or a urinary collection bag. Preferably, the slack tube is pro-

vided with a structure which is different from the structure of the oblong member. In particular, the slack tube is much more flexible than the oblong member, thus allowing the slack tube to be rolled or folded or in any similar way to be arranged in a configuration wherein it takes up least space. The slack tube may be ex-
5 truded from the oblong member and thereby constitutes an integral part of the oblong member. Alternatively, a slack tube may be made separately from the oblong member for subsequent assembling therewith, e.g. by gluing or welding of the slack tube to the oblong member. The slack tube may be made from the same or a similar material as the oblong member. However, preferably, so that
10 the slack tube is less rigid than the oblong member. The slack tube may have a structure which is similar to the structure of a balloon or a condom, i.e. the thickness of the slack tube wall may be a fraction of a millimetre. Such a structure provides virtually no resistance towards bending or folding. The length of the slack tube could be such that the tube extends beyond the external opening of
15 the urinary canal when the corresponding oblong member is in a position wherein it opens the sphincter. At this distal end of the slack tube, connecting means for connecting the tube e.g. to a collection bag for collection of urine, may be provided. In order to allow easy connection of the slack tube to a collection bag, the slack tube may be longer than the guide member. The device may be delivered
20 to the customer in a configuration, wherein the slack tube is rolled up like a condom. During use, the oblong member is inserted into the urethra and, by means of the guide member, it is pushed to a position wherein the sphincter is opened and urine starts to drain. During the insertion operation, the slack tube is unrolled and before the sphincter is passed and urine starts to flow through the slack tube,
25 the distal end thereof may be connected to a place of disposal, e.g. a urinary collection bag.

In order to further ease manipulation of the device, especially the removal of the oblong member, the slack tube may comprise gripping means allowing the user
30 to grip the slack tube for removing the oblong member from a urinary canal. The gripping means may comprise a ring adhered or welded to the slack tube, or the gripping means may be a section with a surface structure so that a high friction is

obtained to aid a better grip. The high frictional section should preferably be limited to a part of the device which is not inserted into the urinary canal. For a device comprising a slack tube, a guide member may be necessary in order to insert the oblong member whereas the slack tube itself may be used for the removal of the oblong member from the urinary canal. Furthermore, the guide member may hinder the extraction of the oblong member and it may hinder the passage of the urine through the urinary canal. Therefore, it may be advantageous that the guide member can be detached from the oblong member once the oblong member is in place in the urethral sphincter.

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The slack tube may also comprise connection means, for connecting the slack tube, e.g., to a collecting reservoir. In one simple embodiment, the connection means could be a conical member similar to connectors for a urinary catheter. In an alternative embodiment, the connection means could comprise a more sophisticated snap locking arrangement, e.g. of the kind known from the LuerLock™ system for medical hoses.

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In order to ease the insertion, at least the part including the oblong member may have a surface with low frictional characteristics. On this part, the surface could correspond to the surface of a regular gel-lubricated catheter, a hydrophilic catheter or any catheter known *per se*. If the device comprises a slack tube, also the surface of the slack tube may be low frictional. However, in order to improve manipulation of the device, the guide member and/or the slack tube or at least the non-insertable parts thereof may be provided with a non-slippery characteristic.

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It is an object of the present invention to provide a device which is easy and discrete to convey and dispose. According to one embodiment, the device may therefore be provided with a guiding member allowing rolling and/or folding e.g. into a substantially circular or substantially elliptical configuration without or at least substantially without causing plastic or permanent deformation of the guide member. Also, it may be an advantage to provide the oblong member in a mate-

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rial and/or a shape supporting bending or rolling up or folding of the oblong member for storage in a shorter and more discrete configuration.

Preferably, the device is packed for storage and delivery to the user in the rolled configuration, and, preferably, the device is adapted to unroll upon opening of the package. I.e. the guide member could preferably be so flexible that it, after unpacking, automatically takes, or at least supports easily configuration into a shape wherein it can be used for guiding the oblong member through the urinary canal to the sphincter, e.g. a substantially straight configuration.

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Detailed description of the invention

Preferred embodiments of the invention will now be described in details with reference to the drawing in which:

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Fig. 1 illustrates a first embodiment of the invention,

Fig. 2 illustrates a second embodiment of the invention,

20 Fig. 3 illustrates the invention comprising a slack tube,

Fig. 4 illustrates the invention wrapped in a package,

Fig. 5 illustrates an alternative embodiment of a device including a guiding device, and

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Fig. 6. Illustrates an alternative cross-sectional shape of the oblong member.

In Fig. 1a a preferred embodiment of a device for opening a human bladder is shown. The device comprises an oblong member 1 made from a flexible polymer material. The oblong member is inserted into urethra in order to open the sphinc-

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ter for voiding the bladder. The oblong member is attached to a guide member 2, made out of a flexible polymer. To facilitate the manipulation of the device, i.e. the insertion and retraction of the device, the guide member is provided with a gripping means 3. The oblong member comprises grooves 4, urine is drained
5 from the bladder through these grooves, since conduits are formed between the outer surface of the grooves and the inner surface of the urine canal. Urine thus starts to flow along the grooves when the tip of the oblong member is inside the bladder. The length of the oblong member is such that it is longer than the urethral sphincter, after passage of the sphincter the urine flows along the urine canal. In Fig. 1b is shown a cross-section 6 of the oblong member obtained along the line 5 in Fig. 1a. In this example, three grooves 7 are intertwined and running along the oblong member, however, any number of intertwined grooves can be used. In this embodiment, the width of the grooves 7, when seen in a cross-sectional view, widens out from a smaller width 8 towards a larger width 9 in the
10 vicinity of the periphery 10 of the oblong member.
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In Fig 2 another preferred embodiment of the device is sketched. The difference with respect to the embodiment shown in Fig 1a is that the conduit 21 provided by the oblong member 20, consist of an inner canal connected to two inlets 22 in
20 the tip of the oblong member. Thus in this embodiment the oblong member is hollow. Upon insertion of the oblong member in the urethral sphincter, the bladder will start to be voided when the inlets reach the inside of the bladder, and urine will pass through the sphincter along the conduit 21 and flow into the urine canal via the outlet 23 in the oblong member. Two inlets are shown, but one, three or
25 more inlets may also be used. The edge around the opening 23 should preferably be smoothly rounded in order not to damage the mucosal lining during use.

In Fig. 3a the device of Fig. 1a is further equipped with a slack tube 30. The slack tube has been extruded from the oblong member and therefore it is an integral
30 part of the oblong member. The slack tube is thus also made from the same material as the oblong member, i.e. a polymer material. The thickness of the slack tube wall is only a fraction of a millimetre. The texture of the slack tube is to be

compared with that of a strong plastic bag, and it provides virtually no resistance towards bending or folding. In Figs. 3b and 3c two features which can be added to the slack tube are shown. These features may also both be added to a single slack tube. In Fig 3b a gripping means 31 has been added. A plastic ring has
5 been adhered either by gluing, or by welding it to the slack tube. By gripping the ring it may be easier to extract the device from the urethra. In Fig. 3c a connection means 32 has been added. The connection means can be used for connecting the slack tube to a reservoir for collecting the urine.

- 10 In Fig. 4, the device 40 of Fig 3a is shown in a package 41 prior to use. The guide member is made in such a way that the elasticity of the guide member allows the member to be rolled into a rolled configuration, which is maintained while the device is wrapped in a package, but upon opening of the package the guide member is adapted to unroll, or to be unrolled. Thus the present invention provides a
15 device for catheterization which is very handy to store or to bring along especially in comparison with existing catheters for male users, which may be more than 30 cm long, and which do not support bending.

- Fig. 5a sketches a guiding device 50 for guiding the guiding member and for
20 guiding the urine to an outlet for controlled drainage of the bladder. The sealing penetration 51 provides a liquid tight seal between the guiding device and the guide member 52. During use, the sealing member 53 is brought into a sealing connection with the opening of the urinary canal of the user. The flange 58 ensures against unintended insertion of the guiding device into the urinary canal.
25 Subsequently, the oblong member 54 is pushed into the urinary canal by the guiding member 52 until urine starts to drain. The urine drains through the urinary canal into the inlet opening 55 and further through the conduit 56 of the guiding device to the outlet 57. From the outlet, the urine may be drained into a place of disposal, e.g. into a urinary collection bag. For that purpose, the outlet may be
30 provided with a flange for connection to a collection bag. The inlet as well as the outlet may, until use, be closed by a sealing cap. The inlet as well as the outlet may be provided with means for connecting the cap, a bag or an ampoule of wa-

ter or similar lubricating substance. Furthermore, the openings could be sealed, e.g. by a foil. In this way, the device may be delivered under sterile conditions to the user, e.g. together with an amount of a lubricating substance, water or a gel, comprised in the conduit 56 of the guiding device. In this regards, the guiding member 52, may be sterile sealed within a compartment 59, e.g. within a bag formed from a thin foil. The sealing penetration 51 and/or the outlet 57 may be located anywhere on the guiding device, e.g. as shown in Fig. 5a or 5b.

Fig. 5b, an embodiment of the guiding device including a receptacle in the form of a urinary collection bag is sketched. In this embodiment, the oblong member 61 and the guide member 62 may be enclosed in the receptacle formed by the urinary collection bag 63 and the guiding device 64. During use, the urine is drained directly into the collection bag and, accordingly, the transition between the collection bag and the guiding device is not necessarily sealed. In case the oblong member is to be stored in a friction reducing substance, a seal between the guiding device and the collection bag may preferably be provided. Such a seal may be broken in connection with insertion of the oblong member into the urinary canal, e.g. automatically upon removal of the oblong member from the guiding device.

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Fig. 6 shows a cross-sectional view of an alternative embodiment of the oblong member 65. In this embodiment, the width of at least a part of the grooves 66, when seen in a cross-sectional view, narrows down from a larger width 67 towards a smaller width 68 in the vicinity of the periphery 69 of the oblong member. As an alternative, the width may be constant in radial direction.

In the above mentioned embodiments, the design has been focused on a catheter-like device for male users. However, the device can likewise be used by female user, with or without modifications. Due to the shorter length of the female urethra, a shorter guide member may be provided to female users. Such shorter guide members further enhance the abilities to arrange the device in a discreet and less notable configuration.

Claims

1. A device for opening a human bladder comprising:

- 5 – an oblong member for opening the urethral sphincter, and
- a flexible guide member for manipulating the oblong member,

wherein the oblong member is shorter than the guide member, and the oblong member comprises means for draining fluid from the bladder.

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2. A device according to claim 1, wherein the guide member is fixed to the oblong member.

3. A device according to claim 1, wherein the guide member is attachable to the
15 oblong member.

4. A device according to any of the preceding claims, wherein the oblong member comprises at least one conduit for draining fluid from the bladder, and wherein the conduit is formed exteriorly between a urinary canal of a catheter user and
20 the catheter.

5. A device according to any of claims 1-3, wherein the oblong member comprises a canal with at least one inlet opening and at least one outlet opening allowing drainage of the bladder through the canal.

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6. A device according to any of the preceding claims, wherein the guide member is made of metal or from a polymer material or from a composite material.

7. A device according to any of the preceding claims, wherein the guide member
30 comprises gripping means.

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8. A device according to any of the preceding claims, wherein the device further comprises a slack tube.

9. A device according to claim 8, wherein the slack tube and the oblong member
5 is provided in one piece.

10. A device according to claim 8 or 9, wherein the slack tube is made from a polymer material.

10 11. A device according to any of the claims 8-10, wherein the oblong member is more rigid than the slack tube.

12. A device according to any of the claims 8-11, wherein the slack tube is longer than the guide member.

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13. A device according to any of the claims 8-12, wherein the slack tube comprises gripping means allowing the user to grip the slack tube for removing the oblong member from a urinary canal.

20 14. A device according to any of the claims 8-13, wherein the slack tube comprises connection means, for connecting the slack tube to peripheral objects.

15. A device according to any of the preceding claims, wherein at least part of the device is provided with a surface which is hydrophilic.

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16. A device according to any of the preceding claims, wherein the guide member allows storage in a rolled configuration.

17. A device according to claim 16, packed in the rolled configuration, wherein
30 the guide member is adapted to unroll upon un-packaging of the device.

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18. A device according to any of the preceding claims, wherein the oblong member is solid.

19. A device according to any of the preceding claims, wherein the oblong member allows storage in a bend configuration.

20. A device according to any of the preceding claims, further comprising a guiding device with a compartment for guiding drained urine, the guiding device being adapted to convey the oblong member from the compartment and into a urinary canal.

21. A device according to claim 20, further comprising a receptacle in fluid communication with the compartment of the guiding device.

22. A device according to claim 20 or 21, further comprising sealing means to seal between the compartment and the urinary canal.

23. A device according to claim 21 or 22, wherein the receptacle is formed in a flexible material allowing manipulation of the guide member through a wall of the receptacle.

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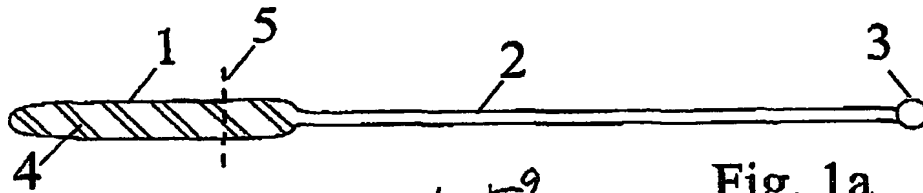


Fig. 1a

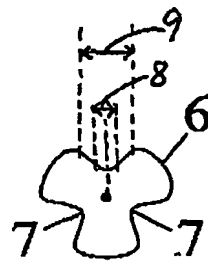


Fig. 1b

Fig. 1

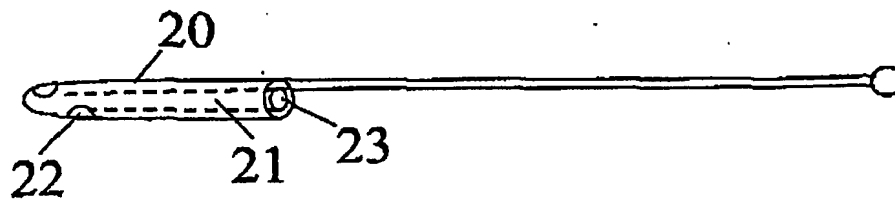


Fig. 2

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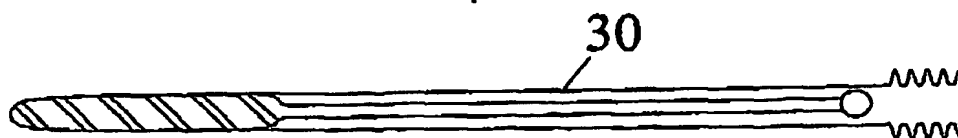


Fig. 3a

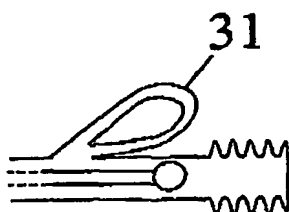


Fig. 3b

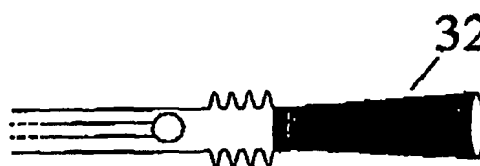


Fig. 3c

Fig. 3

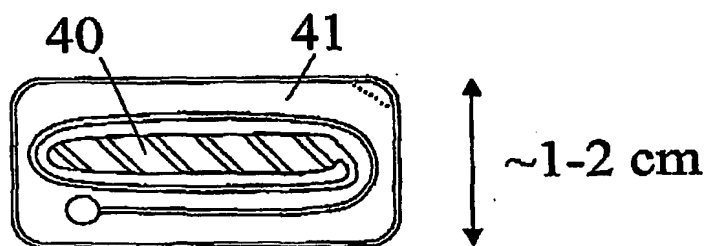


Fig. 4

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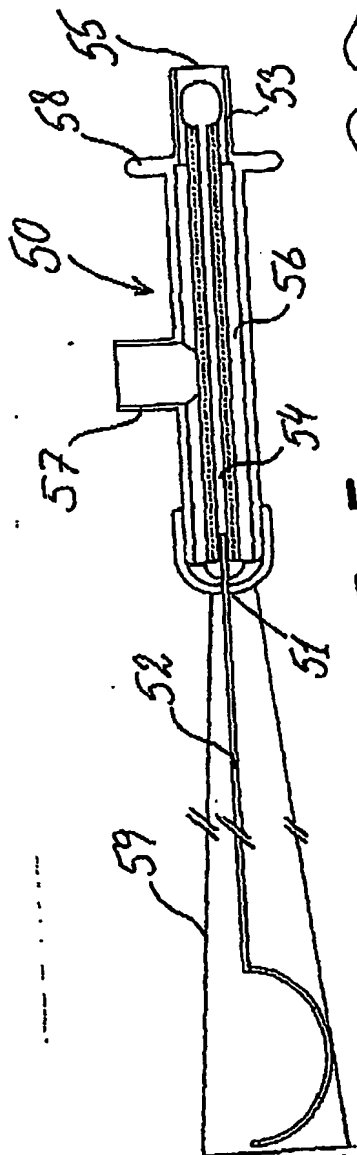


Fig. 5a

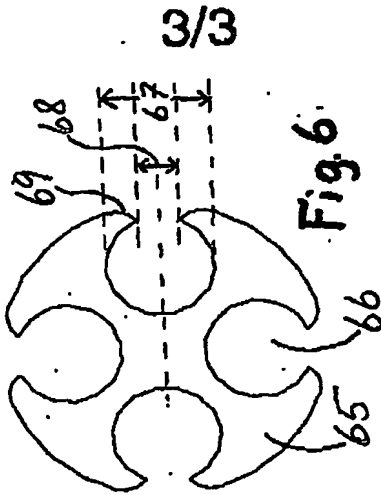


Fig. 6

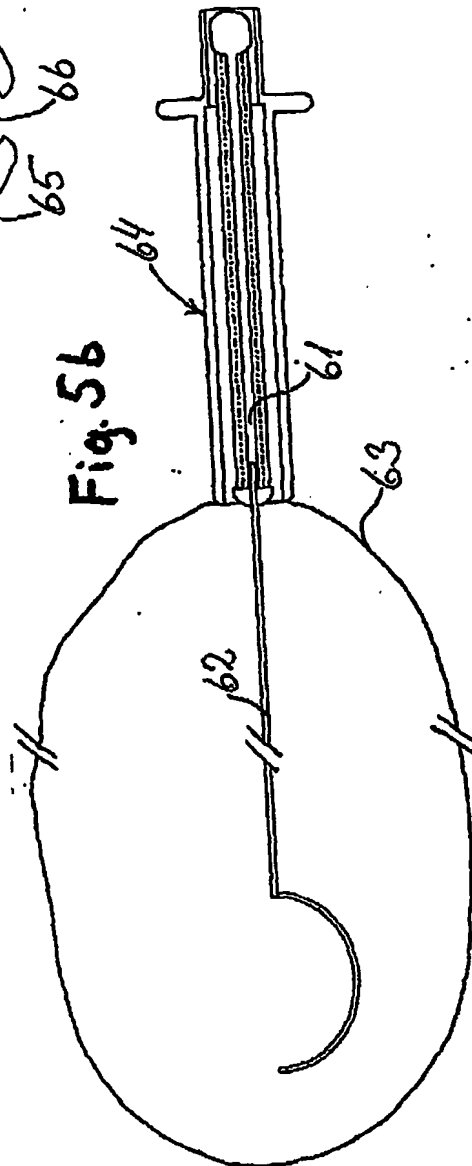


Fig. 5b